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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,272	12/19/2005	Michael Stefanidakis	0933-0260PUS1	5905

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BIRCH STEWART KOLASCH & BIRCH  
PO BOX 747  
FALLS CHURCH, VA 22040-0747

EXAMINER
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RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

NOTIFICATION DATE	DELIVERY MODE
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03/19/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/561,272	<b>Applicant(s)</b> STEFANIDAKIS ET AL.	
	<b>Examiner</b> Jeffrey E. Russel	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20051219</u> .  | 6) <input type="checkbox"/> Other: _____                          |

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1. The Sequence Listing filed September 10, 2007 is approved.

2. Acknowledgment is made of applicant's claim for foreign priority based on Finnish application nos. 20030923 and 20040616 filed on June 19, 2003 and April 29, 2004, respectively. Contrary to the Notice Of Acceptance Of Application Under 35 U.S.C. 371 and 37 CFR 1.495 mailed February 25, 2008, certified copies of these foreign priority applications are not present in the Image File Wrapper for this national stage application. It is further noted that the Filing Receipts mailed January 22, 2007 and February 25, 2008 list incorrect serial numbers and filing dates for the foreign priority applications in the Foreign Applications section. Finally, although usually the examiner is able to obtain copies of foreign priority applications from the EPO website for scanning into the Image File Wrapper for national stage applications, the priority application which is present in the EPO website for application PCT/FI04/00376 is a US provisional application and is not either one of the two Finnish priority applications cited by Applicants in their declaration. It will be necessary for Applicants to submit certified copies of the foreign priority applications in order to perfect their claim for priority under 35 U.S.C. 119(a)-(d).

3. The disclosure is objected to because of the following informalities: A SEQ ID NO must be inserted after the amino acid sequence recited at page 4, line 18, of the specification. See 37 CFR 1.821(d). Appropriate correction is required.

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6 and 7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A "Use" is not a statutory class of invention.

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5. Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what constitutes a “Use” is recited in instant claims 6 and 7. It is not clear if Applicants are claiming, e.g., a product with an intended use limitation, or a method of using a product. To the extent that the latter may be intended, the claims are indefinite because they are drawn to a method of use, but do not recite any positive process steps.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Wu et al (U.S. Patent Application Publication 2003/0109021). Wu et al teach MMP-29, which comprises the hexapeptide motif HFDDDE at residues 259-264. See, e.g., Figure 2A; SEQ ID NO:2; and claim 5. Wu et al also teach an MMP-29 catalytic domain polypeptide, which also comprises the hexapeptide motif HFDDDE at residues 99-104. See, e.g., page 24, paragraph [0236], and SEQ ID NO:76. Wu et al teach the polypeptides in combination with pharmaceutically acceptable carriers. See, e.g., pages 124-125, paragraph [1167]. Wu et al teach the use of MMP-29 to treat diseases including inflammatory diseases. See, e.g., page 3, paragraph [0053]; page 12, paragraph [0149]; page 82, paragraph [0675]; and claims 10 and 18. With respect to instant claims 2-4, 6, and 7, note also that an intended use limitation does not impart patentability to a product claim where the product is otherwise anticipated by the prior art. With respect to instant

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claims 8 and 9, because the same active agent is being administered to the same subject in order to prevent or treat the same diseases in the method of Wu et al and in Applicants' claimed method, inherently conditions dependent on neutrophil migration will be prevented, and inherently neutrophil migration will be inhibited, in the method of Wu et al to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the method of Wu et al and Applicants' claimed method to shift the burden to Applicants to provide evidence that the claimed method is unobviously different than the method of Wu et al.

8. Claims 1-9 are rejected under 35 U.S.C. 102(a) as being anticipated by the Stefanidakis et al article (J. Immunol., Vol. 172, No. 11, pages 7060-7068). The Stefanidakis et al article teaches the hexapeptide HFDDDE. The hexapeptide is injected in vivo into mice in order to prevent migration of neutrophils into inflammatory tissue. See, e.g., page 7061, column 1, last full paragraph, and Figure 7.

The website for the Journal of Immunology gives a publication date of June 1, 2004 for the Volume 172, Number 11 issue of the Journal of Immunology.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications

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such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/

Primary Examiner, Art Unit 1654

JRussel

March 20, 2008